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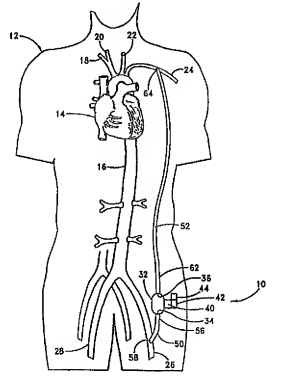
(54) Title: HEART ASSIST SYSTEM

(57) Abstract

An extracardiac pumping (10) for supplementing the circulation of blood, including the cardiac output, in a patient without any component thereof being connected to the patient's heart. One embodiment of the extracardiac system comprises a pump (32) implanted subcutaneously at or about the patient's femoral artery in a minimally-invasive procedure, wherein the pump is powered by a battery (44), and mechanism for charging the battery extracorporeally, whereby the pump draws blood through an inflow conduit (50) fluidly coupled to the patient's femoral artery via, for example, a subcutaneous anastomosis connection, and discharges blood through an outflow conduit (52) fluidly coupled to a second peripheral artery via, for example, a subcutaneous anastomosis connection. The pump may be operated in continuous flow mode, or in a pulsatile fashion synchronous with the patient's heart, thereby potentially reducing the afterload of the heart. The conduits (50, 52) can be in fluid communication with a multi-lumen catheter (510) for single point application of the system to the patient. If desired, a reservoir (410) may be provided fluidly communicating with the inflow conduit. The system may also comprise a device (402) for keeping the blood travelling extracorporeally within the system at or near body temperature. If further desired, the present system may be carried directly on the patient with a device (610) that holds at least the pump and is carried by a belt or a shoulder strap.



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HEART ASSIST SYSTEM

Field Of The Invention

The present invention relates generally to a system for assisting the heart and, in particular, to an extracardiac pumping system and a method for both supplementing the circulation of blood through the patient and for enhancing vascular blood mixing using a minimally invasive procedure.

Background Of The Invention

During the last decade, congestive heart failure (CHF) has burgeoned into the most important public health problem in cardiovascular medicine. As reported in Gilum, R. F., *Epidemiology of Heart Failure in the U. S.*, 126 Am. Heart J. 1042 (1993), four hundred thousand (400,000) new cases of CHF are diagnosed in the United States annually. The disorder is said to affect nearly 5 million people in this country and close to 20 million people worldwide. The number of hospitalizations for CHF has increased more than three fold in the last 15 years. Unfortunately, nearly 250,000 patients die of heart failure annually. According to the Framingham Heart Study, the 5-year mortality rate for patients with congestive heart failure was 75 per cent in men and 62 per cent in women (Ho, K. K. L., Anderson, K. M., Kannel, W. B., et al., *Survival After the Onset of Congestive Heart Failure in Framingham Heart Study Subject*, 88 Circulation 107 (1993)). This disorder represents the most common discharge diagnosis for patients over 65 years of age. Although the incidence of most cardiovascular disorders has decreased over the past 10 to 20 years, the incidence and prevalence of congestive heart failure has increased at a dramatic rate. This number will increase as patients who would normally die of an acute myocardial infarction (heart attack) survive, and as the population ages.

CHF manifests itself primarily by exertional dyspnea (difficult or labored breathing) and fatigue. Three paradigms are used to describe the causes and therapy of CHF. The first views this condition in terms of altered pump function and abnormal circulatory dynamics. Other models describe it largely in terms of altered myocardial cellular performance or of altered gene expression in the cells of the atrophied heart. In its broadest sense, CHF can be defined as the inability of the heart to pump blood throughout the body at the rate needed to maintain adequate blood flow, and many of the normal functions of the body.

To address CHF, many types of cardiac assist devices have been developed. A cardiac or circulatory assist device is one that aids the failing heart by increasing its pumping function or by allowing it a certain amount of rest to recover its pumping function. Because congestive heart failure may be chronic or acute, different categories of heart assist devices exist. Short of a heart transplant, at least two types of chronic heart assist systems have been developed. One type employs a full or partial prosthetic connected between the heart and the aorta, one example of which is commonly referred to as a LVAD - Left Ventricular Assist Device. With reference to Figure 1 herein, one example of a LVAD 2 is shown. The LVAD comprises a pump and associated valves 4 that draws blood directly from the apex of the left ventricle 6 and directs the blood to the aortic arch 8, bypassing the aortic valve. In this application, the left ventricle stops functioning and does not contract or expand. The left ventricle becomes, in effect, an extension of the left atrium, with the LVAD 2 taking over for the left ventricle. The ventricle, thus, becomes a low-pressure chamber. Because the intent is to take over for the left ventricle, the LVAD operates by pumping blood at cardiac rates. With an LVAD, oxygenated blood circulation is established sufficient to satisfy the demand of the patient's organs. Under these circumstances, however, continuous flow may not be desired because the patient's arterial system is deprived of pulsatile wave flow, which is beneficial to certain parts of the patient.

Another type of chronic heart assist system is shown in U. S. Patent No. 5,267,940 to Moulder. Moulder describes a pump implanted into the proximal descending aorta to assist in the circulation of blood through the aorta. Because it is intended to pump blood flowing directly out of the heart, it is important that the Moulder device operate in a properly timed, pulsatile fashion. If it is not

operated in direct synchronization with the patient's heart, there is a risk that the pump might cause "carotid steal phenomenon" where blood is drawn away from the patient's brain through the carotid arteries when there is insufficient blood in the left ventricle.

In addressing acute CHF, two types of heart assist devices have been used. One is counterpulsatory in nature and is exemplified by an intra-aortic balloon pump (IABP). With an IABP, the balloon is collapsed during isovolumic contraction, providing a reduced pressure against which the heart must pump blood, thereby reducing the load on the heart during systole. The balloon is then expanded, forcing blood omnidirectionally through the arterial system. Another example of this first type employs one or more collapsible chambers in which blood flows passively into the chamber during systole, as is shown in U. S. Patent No. 4,240,409 to Robinson et al. The chamber is then collapsed and the blood forcibly returned to the aorta. These devices simulate a chamber of the heart and depend upon an inflatable bladder to effectuate pumping action, requiring an external pneumatic driver. Moreover, they do not operate as a continuous flow system, operating exclusively in pulsatile fashion.

A second type of acute assist device utilizes an extracorporeal pump, such as the Biomedicus centrifugal pump, to direct blood through the patient while surgery is performed on the heart. In one example, described in U. S. Patent No. 4,968,293 to Nelson, the heart assist system employs a centrifugal pump in which the muscle of the patient is utilized to add pulsatility to the blood flow. The Nelson device is used to bypass a portion of the descending aorta.

Another device, shown in U. S. Patent No. 4,080,958 to Bregman et al., utilizes an inflatable and collapsible bladder to assist in blood perfusion during heart trauma and is intended to supplement a conventional heart-lung machine by imparting pulsatile actuation. In the primary embodiment disclosed in Bregman, the balloon is controlled to maintain sufficient pressure at the aortic root during diastole to ensure sufficient blood perfusion to the coronary arteries. In an alternative embodiment, a low resistance outlet from the aorta to the inferior vena cave is provided to reduce the aortic pressure during systole, thus, reducing the hemodynamic load on the left ventricle.

Other devices, such as that shown in U. S. Patent No. 4,034,742 to Thoma, depend upon interaction and coordination with a mechanical pumping chamber containing a movable pumping diaphragm. These devices are intended primarily for application proximate the heart and within the patient's thorax, requiring major invasive surgery.

Many CHF devices are acutely used in the perioperative period. For example, U. S. Patent No. 4,995,857 to Arnold discloses a perioperative device to pump blood at essentially cardiac rates during surgery when the heart has failed or has been stopped to perform cardiac surgery. The Arnold system temporarily replaces the patient's heart and lung and pumps blood at cardiac rates, typically 5 to 6 liters/min. Like all systems that bypass the heart and the lungs, an oxygenator is required. Of course, with any system that includes an oxygenator, such as the conventional heart-lung machine, the patient cannot be ambulatory.

With early IABP devices, a polyurethane balloon was mounted on a vascular catheter, inserted into the femoral artery, and positioned in the descending aorta just distal to the left subclavian artery. The balloon catheter was connected to a pump console that pumped helium or carbon dioxide into the balloon during diastole to inflate it. During isovolumic contraction, i. e., during the brief time that the aortic valve is closed and the left ventricle continues to contract, the gas used to actuate the balloon was rapidly withdrawn to deflate the balloon. This reduced the pressure at the aortic root when the aortic valve opened. In contrast, during diastole, the balloon was inflated, causing the diastolic pressure to rise and pushing the blood in the aorta distally towards the lower part of the body (on one side of the balloon) and proximally toward the heart and into the coronary arteries (on the other).

The major advantage in such a counterpulsation device was systolic deflation, which lowered the intra-aortic volume and pressure, reducing both afterload and myocardial oxygen consumption. In other words, when the balloon is inflated, it creates an artificially higher pressure in the aorta, which has the ancillary benefit of greater perfusion through the coronary arteries. When the

balloon deflates, just before the aortic valve opens, the pressure and volume of the aorta decrease, relieving some of the hemodynamic burden on the heart. These physiologic responses improved the patient's cardiac output and coronary circulation, temporarily improving hemodynamics. In general, counterpulsation with an IABP can augment cardiac output by about 15%, this being frequently sufficient to stabilize the patient's hemodynamic status, which might otherwise rapidly deteriorate. When there is evidence of more efficient pumping ability by the heart, and the patient has moved to an improved class of hemodynamic status, counterpulsation can be discontinued, by slowly weaning while monitoring for deterioration.

Until 1979, all IABP catheters were inserted via surgical cutdown, generally of the femoral artery. Since then, the development of a percutaneous IABP catheter has allowed quicker, and perhaps safer, insertion and has resulted in more expeditious institution of therapy and expansion of clinical applications. Inflation and deflation of the balloon, however, requires a pneumatic pump that is sufficiently large that it must be employed extracorporeally, thereby restricting the patient's movements and ability to carry out normal, daily activities. IABP devices are, thus, limited to short term use, on the order of a few days to a few weeks.

As discussed above, a variety of ventricular assist pumping mechanisms have been designed. Typically associated with LVADs are valves that are used in the inlet and outlet conduits to insure unidirectional blood flow. Given the close proximity of the heart, unidirectional flow was necessary to avoid inadvertent backflow into the heart. The use of such valves also minimized the thrombogenic potential of the LVAD device.

Typically, the pump associated with older LVADs was a bulky pulsatile flow pump, of the pusher plate or diaphragm style, such as those manufactured by Baxter Novacor or TCI, respectively. Given that the pump was implanted within the chest and/or abdominal cavity, major invasive surgery was required. The pumps were typically driven through a percutaneous driveline by a portable external console that monitors and reprograms functions.

Alternatively, rotary pumps, such as centrifugal or axial pumps, have been used in heart assist systems. With centrifugal pumps, the blood enters and exits the pump practically in the same plane. An axial pump, in contrast, directs the blood along the axis of rotation of the rotor. Inspired by the Archimedes screw, one design of an axial pump has been miniaturized to about the size of a pencil eraser, although other designs are larger. Despite its small size, an axial pump may be sufficiently powerful to produce flows that approach those used with older LVADs. Even with miniaturized pumps, however, the pump is typically introduced into the left ventricle through the aortic valve or through the apex of the heart, and its function must be controlled from a console outside the body through percutaneous lines.

All of these heart assist systems referred to above serve one or both of two objectives: (1) to improve the performance of a patient's operative-but-diseased heart from the minimum, classified as NYHAC Class IV, to practically normal, classified as I or II; or (2) to supplement oxygenated blood circulation through the patient to satisfy organ demand when the patient's heart is suffering from CHF. With such systems, extreme pumping and large amounts of energy, volume, and heat dissipation are required.

Many of these heart assist systems have several general features in common: 1) the devices are cardiac in nature; i. e., they are placed directly within or adjacent to the heart, or within one of the primary vessels associated with the heart (aorta), and are often attached to the heart and/or aorta; 2) the devices attempt to reproduce pulsatile blood flow naturally found in the mammalian circulatory system and, therefore, require valves to prevent backflow; 3) the devices are driven from external consoles, often triggered by the electrocardiogram of the patient; and 4) the size of the blood pump, including its associated connectors and accessories, is generally unmanageable within the anatomy and physiology of the recipient. Due to having one or more of these features, the prior art heart assist devices are limited in their effectiveness and/or practicality.

Many of the above identified prior art systems, generally referred to as Mechanical Circulatory Assist Devices, are not the only means, however, used to treat patients with congestive heart failure (CHF). Most CHF patients are prescribed as many as five to seven different drugs to ameliorate their signs and symptoms. These drugs may include diuretics, angiotensin converting enzyme (ACE) inhibitors, beta-blockers, cardiac glycosides, and peripheral vasodilators. The rationale for pharmacologicel intervention in heart failure include minimizing the load on the heart, improving the pumping action of the heart by enhancing the contractility of the muscle fibers, and suppression of harmful neurohormonal compensatory mechanisms that are activated because of the decreased pumping function of the heart.

Noncompliance with what is often a complex drug regime may dramatically adversely affect the recovery of a CHF patient leading to the need for hospitalization and possibly morbidity and mortality. In addition, ACE inhibitors and diurectics can cause hypotension, which leads to decreased organ perfusion or an increasing demand on the heart to pump more blood. This leads to an inability, in many cases, to prescribe the most effective dosage of ACE inhibitors and a less than optimum outcome for the patient. Patients suffering from CHF with the underlying cause of mitral valve insufficiency have been able to have their diuretics reducad following surgical repair of their mitral valve. This is due to an increased cardiac output and arterial pressures (as a result of the correction of the problem) resulting in more effective organ perfusion. With the reduction in the use of diuretics and the resultant hypotension, more affective dosages of ACE inhibitors can be used with more favorable outcomes. In addition, it is easier for the patient to follow a less complex drug regime, eliminating the costly and life threatening risks associated with noncompliance.

When blood flow through the coronary arteries falls below the level needed to provide the energy necessary to maintain myocardial function, due often to a blockage in the coronary arteries, a myocardial infarction or heart attack occurs. This is a result of the blockage in the coronary arteries preventing blood from delivering oxygen to tissues downstream of the blockage. The closer the blockage is to the coronary ostia, however, the more severe and life threatening the myocardial infarction. The farther the location of the blockage is from the coronary ostia, the smaller the area of tissue or myocardium that is at risk. As the energy stored in the affected area decreases, myocardial cells begin to die. The larger the area that dies due to the loss of oxygen, the more devastating the infarction. To reduce the area at risk, at least two known options are to either increase the oxygen supply to the affected area or decrease the energy demands of the heart to prolong energy stores until the blockage can be removed or reduced. One particular method to increase blood flow, thereby increasing delivery of oxygen to the affected area, is through a technique called retroperfusion. This is accomplished by passing a cannula into either the right or left ventricle (depending on the area of the blockage) and perfusing oxygenated blood retrograde up the coronary artery on the downstream side of the blockage. Another method is to use drugs to increase the force of contraction of the myocardium, creating increased blood flow across the blocked area. Yet another method is to use drugs, such as pentoxifylline, aspirin, or TPA (tissue plaminogen activator), to reduce the viscosity of (thin out) the blood, inhibit platelet aggregation, or lyse thrombi (clots), respectively, thus, allowing more blood to pass by the blockage. The goal of all of these methods is to increase the delivery of oxygen to the tissue at risk.

The alternative option mentioned above is to reduce the energy demands of the myocardium and increase the amount of time before irreversible damage occurs. This can be accomplished by reducing the workload of the left ventricle (which is the largest energy-consuming portion of the heart). An IABP is placed into the aorta and used as described above, resulting in a decreased afterload on the heart and increased perfusion of the coronary arteries and peripheral organs. An alternative way to reduce myocardial oxygen demand is to reduce the volume of blood the left ventricle must pump. This can be accomplished by reducing the load on the left ventricle, such as in a cardiopulmonary bypass or use of an LVAD. Unloading the left ventricle decreases the energy requirements of the myocardium

and increases the amount of time before irreversible damage occurs. This provides an opportunity to more effectively remove or decrease the blockage and salvage myocardial function. To be successful, each of these techniques must be implemented within a short amount of time after the onset of a myocardial infarction. The disadvantage, however, is that each of these techniques can only be performed in an emergency room or hospital setting. Unless the patient is already in the hospital when the myocardial infarction occurs, there is usually some level of irreversible damage and subsequent loss of myocardial function.

It would be advantageous, therefore, to employ a heart assist system that avoids major invasive surgery and also avoids the use of peripheral equipment that severely restricts a patient's movement. It would also be advantageous to have such a heart assist system that can be employed in a non-hospital setting for ease of treating acute heart problems under emergency conditions.

Summary Of The Invention

The object of the present invention is to address the aspect of CHF that results from altered pump function and abnormal circulatory dynamics while overcoming the limitations of prior art heart assist systems. Without functioning as a bypass to one or more of a patient's organs, the present invention comprises an extracardiac pumping system for supplementing the circulation of blood through the patient without any component thereof being connected to the patient's heart or primary vessels. Thus, it is extracardiac in nature. With the ability to be applied within a minimally invasive procedure, the present invention significantly improves the condition of the patient suffering from CHF, resulting in the patient feeling much better, even where CHF continues. By supplementing the pumping action of the heart, in lieu of replacing it, the present system takes advantage of the pulsatile action of the heart, despite its weakened condition, to effectively deliver blood to body organs that benefit from pulsatile delivery of oxygenated blood. As a result, the present system is capable of being operated in a continuous flow fashion or, if desired, in a pulsatile flow fashion.

An ancillary but important benefit of the present invention is the ability to apply the present invention in such a way as to also reduce the pumping load on the heart, thereby potentially permitting the heart to recover during use. With the present invention, no bulky pump, valves or oxygenator are required, and no thoracic invasion with major cardiac surgery is required. Indeed, a significant advantage of the present invention is its simplicity while achieving extraordinary results in improving the condition of a patient suffering from CHF.

The extracardiac system of the present invention preferably comprises, in one example, a rotary pump configured to pump blood through the patient at subcardiac rates; i. e., at a flow rate significantly below that of the patient's heart. Other types of pumps or flow generating mechanisms may be effective as well. Pumping the blood tends to revitalize the blood to a certain extent by imparting kinetic and potential energy to the blood discharged from the pump. Importantly, the preferred pump for the present invention pumping system is one that requires a relatively low amount of energy input, when compared to prior art pumps designed to pump at cardiac rates. The pump may be implanted or not, depending upon the capability, practicality, or need of the patient to be ambulatory.

The present system also comprises an inflow conduit fluidly coupled to the pump, to direct blood to the pump from a first peripheral blood vessel, and an outflow conduit fluidly coupled to the pump, to direct blood from the pump to a second peripheral blood vessel. The connection of the inflow and outflow conduits to the respective blood vessels is performed subcutaneously; not so deep as to involve major invasive surgery. In other words, minimally subdermal. This permits application of the connections in a minimally-invasive procedure. Preferably, the connections to the blood vessels are just below the skin or just below the first layer of muscle, depending upon the blood vessels at issue or the location of the connection, although slightly deeper penetrations may be necessary for some patients or for some applications.

In an alternative embodiment, the present system is applied at a single cannulated site using, for example, a multi-lumen catheter having at least one lumen as an inflow lumen and a second lumen as an outlet lumen. The multi-lumen catheter has an inflow port in fluid communicating with the inflow lumen. With this embodiment, blood is drawn into the inflow port of the first lumen from a first peripheral blood vessel site, preferably the blood vessel into which the multi-lumen catheter is inserted. The output of the pump directs blood through a second (outlet) port at the distal end of the second lumen that is preferably located in a second peripheral vessel site. This method accomplishes the same beneficial results achieved in the previously described embodiments, but requires only a single cannulated site, rather than two such sites. It should be appreciated that the multi-lumen catheter could be used in a manner where the outflow of the cannula is to the first peripheral site, while the inflow is drawn from the second peripheral vessel. Further still, it should be appreciated that the inflow could be positioned to draw blood from a peripheral vessel at the site of entry into the patient while the outflow could be positioned in the aorta, proximate an arterial branch.

In one embodiment of the extracardiac system, the pump is a continuous flow pump, a pulsatile pump, and/or a pump that is configured to generate flow in both a continuous and pulsatile format. The pump may be implantable and is used to connect two peripheral arteries, such as the femoral artery at the inflow and the left axillary artery at the outflow, although other peripheral blood vessels are contemplated, including other arteries and/or veins, as well as any singular and/or cumulative combination thereof. An alternative embodiment employs both a continuous flow and a pulsatile flow pump connected in parallel or in series and operating simultaneously or in an alternating fashion. Yet another alternative embodiment employs a rotary pump that is controllable in a synchronous copulsating or counterpulsating fashion, or in some out-of-phase intermediate thereof. In one application, it is contemplated that the present invention be applied such that the heart experiences a reduced pressure at the aortic root during systole (afterload) and/or a reduced left ventricular end diastolic pressure (pre-load), thus reducing the hemodynamic burden or workload on the heart and, thus, permitting the heart to recover.

It is contemplated that, where the entire system of the present invention is implanted, that it be implanted subcutaneously without the need for major invasive surgery and, preferably, extrathoracically. For example, the pump may be implanted in the groin area, with the inflow conduit attached to the femoral or iliac artery proximate thereto and the outflow conduit attached to the axillary artery proximate the shoulder. It is contemplated that the outflow conduit be applied by tunneling it under the skin from the pump to the axillary artery. Where implanted, the pump is preferably powered by an implantable power source, such as for example a battery, that may be regenerated externally by an RF induction system or be replaced periodically, and/or a self-generating power source that, for example, draws energy from the human body (e. g., muscles, chemicals, heat).

The present invention also comprises a method for supplementing the circulation of blood in the patient and potentially reducing the workload on the heart of a patient without connecting any component to the patient's heart. The inventive method comprises the steps of implanting a pump configured to generate blood flow at volumetric rates that are on average subcardiac, wherein the pump has an inflow and outflow conduit attached thereto; connecting a distal end of the inflow conduit to a first peripheral blood vessel with a minimally-invasive surgical procedure to permit the flow of blood to the pump from the first peripheral blood vessel of the patient; implanting the inflow conduit subcutaneously; connecting a distal end of the outflow conduit to a second peripheral blood vessel with a minimally-invasive surgical procedure to permit the flow of blood away from the pump to the second peripheral blood vessel of the patient; and operating said pump to perfuse blood through the patient's circulatory system. Where the second peripheral blood vessel is the axillary artery, the step of connecting the distal end of the outflow conduit is performed in such a manner that a sufficient flow of blood is directed toward the hand to avoid limb ischemia while ensuring that sufficient flow is directed toward the

aorta without damaging the endothelial lining of the second peripheral blood vessel. The same concerns for avoiding limb ischemia and damage to the endothelial lining would apply, however, regardless of the selection of second peripheral blood vessel.

In one specific application, the pump is capable of synchronous control wherein the step of operating the pump includes the steps of beginning discharge of blood out of the pump during isovolumic contraction and discontinuing discharge of blood when the aortic valve closes following systole. Depending upon the patient and the specific arrangement of the present system, this specific method results in reduced afterload and/or preload on the heart while also supplementing circulation. For example, in one embodiment, the first and second blood vessels are the femoral and axillary arteries, respectively.

In an alternative method of applying the present invention, the pump is not implanted and the inflow and outflow conduits are connected to the first and second blood vessels percutaneously, using a readily-removable connector, such as a cannula, to connect the distal ends of each conduit to the blood vessels.

An important advantage of the present invention is that it utilizes the benefits of an IABP, without the requirement of extracorporeal equipment or the need to have a balloon or similar implement partially obstructing a blood vessel. In addition to the benefits of an IABP, it also offers the benefit of reducing the preload on the heart. The present invention thus offers simplicity and long-term use.

Another important advantage of the present invention is its potential to enhance mixing of systemic arterial blood, particularly in the aorta, and thereby deliver blood with a higher oxygen-carrying capacity to organs supplied by arterial side branches off of the aorta. This overcomes the problem of blood streaming in the descending aorta that may sometimes occur in patients suffering from low cardiac output or other ailments resulting in low blood flow. The lack of mixing of the blood within the descending aorta that may result from blood streaming could lead to a higher concentration of red blood cells and nutrients in the central region of the aorta and a decreasing concentration of red blood cells closer to the aortic wall. This could result in lower hematocrit blood flowing into branch arteries from the aorta.. Where it is desired to address the potential problem of blood streaming, a method of utilizing the present invention may include taking steps to assess certain parameters of the patient and then to determine the minimum output of the pump that ensures turbulent flow in the aorta, thereby enhancing blood mixing.

Brief Description Of The Drawings

These and other features and advantages of the invention will now be described with reference to the drawings, which are intended to illustrate and not to limit the invention.

Figure 1 is a schematic view of a cardiac assist device, known as a left ventricular assist device, showing a bypass from the apex of the left ventricle to the aortic arch;

Figure 2 is a schematic view of a first embodiment of the present invention, shown applied to a patient's circulatory system.

Figure 3 is a schematic view of a second embodiment of the present invention, shown applied to a patient's circulatory system.

Figure 4 is a schematic view of a variation of the first embodiment of Figure 2 shown implanted into a patient;

Figure 5 is a schematic view of a third embodiment of the present invention, shown applied to a patient's circulatory system.

Figure 6 is a schematic view of a fourth embodiment of the present invention, shown applied to a patient's circulatory system.

Figure 7 is a schematic view of an inflow L-shaped connector, shown inserted within a blood vessel.

Figure 8 is a schematic view of a fifth embodiment of the present invention employing a multi-lumen catheter for single site application to a patient.

Figure 9 is a schematic view of a sixth embodiment of the present invention showing a reservoir and a portable housing for carrying a portion of the invention directly on the patient.

Detailed Description Of The Preferred Embodiments

Turning now to the drawings provided herein, a more detailed description of the embodiments of the present invention is provided below. It should be noted, however, that while some embodiments have all of the advantages identified herein, other embodiments may only realize some but not all of the advantages.

The present invention provides a heart assist system that is extracardiac in nature. In other words, the present invention supplements blood perfusion, without the need to interface directly with the heart and aorta. Thus, no major invasive surgery is necessary to use the present invention. The present invention also lessens the hemodynamic burden or workload on the heart by reducing the pressure at the aortic root during systole (afterload) and/or reducing left ventricular end diastolic pressure and volume (preload).

With reference to Figure 2, a first embodiment of the present invention 10 is shown applied to a patient 12 having an ailing heart 14 and an aorta 16, from which peripheral brachiocephalic blood vessels extend, including the right subclavian 18, the right carotid 20, the left carotid 22, and the left axillary 24. Extending from the descending aorta is another set of peripheral blood vessels, the left and right femoral arteries 26, 28.

The first embodiment 10 comprises a pump 32, having an inlet 34 and an outlet 36 for connection of flexible conduits thereto. The pump 32 is preferably a rotary pump, either an axial type or a centrifugal type, although other types of pumps may be used, whether commercially-available or customized. In either case, the pump should be sufficiently small to be implanted subcutaneously and preferably extrathoracically, for example in the groin area of the patient, without the need for major invasive surgery. Because the present invention is an extracardiac system, no valves are necessary. Any inadvertent backflow through the pump and/or through the inflow conduit would not harm the patient.

Regardless of the style or nature chosen, the pump 32 of the present invention is sized to generate blood flow at subcardiac volumetric rates, less than about 50% of the flow rate of an average healthy heart, although flow rates above that may be effective. Thus, the pump 32 of the present invention is sized and configured to discharge blood at volumetric flow rates anywhere in the range of 0. 1 to 3 liters per minute, depending upon the application desired and/or the degree of need for heart assist. For example, for a patient experiencing advanced congestive heart failure, it may be preferable to employ a pump that has an average subcardiac rate of 2. 5 to 3 liters per minute. In other patients, particularly those with minimal levels of heart failure, it may be preferable to employ a pump that has an average subcardiac rate of 0. 5 liters per minute or less. In yet other patients it may be preferable to employ a pump that is a pressure wave generator that uses pressure to augment the flow of blood generated by the heart.

In one embodiment, the pump selected is a continuous flow pump so that blood perfusion through the circulation system is continuous. In an alternative embodiment, the pump selected has the capability of synchronous actuation; i. e., it may be actuated in a pulsatile mode, either in copulsating or counterpulsating fashion.

For copulsating action, it is contemplated that the pump 32 would be actuated to discharge blood generally during systole, beginning actuation, for example, during isovolumic contraction before the aortic valve opens or as the aortic valve opens. The pump would be static while the aortic valve is closed following systole, ceasing actuation, for example, when the aortic valve closes.

For counterpulsating actuation, it is contemplated that the pump 32 would be actuated generally during diastole, ceasing actuation, for example, before or during isovolumic contraction. Such an application would permit and/or enhance coronary blood perfusion. In this application, it is contemplated that the pump would be static during the balance of systole after the aortic valve is

opened, to lessen the burden against which the heart must pump. The aortic valve being open encompasses the periods of opening and closing, wherein blood is flowing therethrough.

It should be recognized that the designations copulsating and counterpulsating are general identifiers and are not limited to specific points in the patient's heart cycle when the pump begins and discontinues actuation. Rather, they are intended to generally refer to pump actuation in which the pump is actuating, at least in part, during systole and diastole, respectively. For example, it is contemplated that the pump might be activated to be out of phase from true copulsating or counterpulsating actuation described herein, and still be synchronous, depending upon the specific needs of the patient or the desired outcome. One might shift actuation of the pump to begin prior to or after isovolumic contraction or to begin before or after isovolumic expansion.

Furthermore, the pulsatile pump may be actuated to pulsate asynchronously with the patient's heart. Typically, where the patient's heart is beating irregularly, there may be a desire to pulsate the pump asynchronously so that the perfusion of blood by the extracardiac pumping system is more regular and, thus, more effective at oxygenating the organs. Where the patient's heart beats regularly, but weakly, synchronous pulsation of the extracardiac pump may be preferred.

The pump 32 is driven by a motor 40 and/or other type of drive means and is controlled preferably by a programmable controller 42 that is capable of actuating the pump in pulsatile fashion, where desired, and also of controlling the speed or output of the pump. For synchronous control, the patient's heart would preferably be monitored with an EKG in which feedback would be provided the controller 42. The controller 42 is preferably programmed by the use of external means. This may be accomplished, for example, using RF telemetry circuits of the type commonly used within implantable pacemakers and defibrillators. The controller may also be autoregulating to permit automatic regulation of the speed, and/or regulation of the synchronous or asynchronous pulsation of the pump, based upon feedback from ambient sensors monitoring parameters, such as pressure or the patient's EKG. It is also contemplated that a reverse-direction pump be utilized, if desired, in which the controller is capable of reversing the direction of either the drive means or the impellers of the pump. Such a pump might be used where it is desirable to have the option of reversing the direction of circulation between two peripheral blood vessels.

Power to the motor 40 and controller 42 may be provided by a power source 44, such as a battery, that is preferably rechargeable by an external induction source (not shown), such as an RF induction coil that may be electromagnetically coupled to the battery to induce a charge therein. Alternative power sources are also possible, including a device that draws energy directly from the patient's body; e. g., the patient's muscles, chemicals or heat. The pump can be temporarily stopped during recharging with no appreciable life threatening effect, because the system only supplements the heart, rather than substituting for the heart.

While the controller 42 and power source 44 are preferably pre-assembled to the pump 32 and implanted therewith, it is also contemplated that the pump 32 and motor 40 be implanted at one location and the controller 42 and power source 44 be implanted in a separate location. In one alternative arrangement, the pump 32 may be driven externally through a percutaneous drive line. In another alternative, the pump, motor and controller may be implanted and powered by an extracorporeal power source. In the latter case, the power source could be attached to the side of the patient to permit fully ambulatory movement.

The inlet 34 of the pump 32 is preferably connected to a flexible inflow conduit 50 and a flexible outflow conduit 52 to direct blood flow from one peripheral blood vessel to another. The inflow and outflow conduits 50, 52 may, for example, be formed from Dacron, Hemashield or Gortex materials, although other synthetic materials may be suitable. The inflow and outflow conduits 50, 52 may also comprise biologic materials or pseudobiological (hybrid) materials (e. g., biologic tissue supported on a synthetic scaffold). The inflow and outflow conduits are preferably configured to minimize kinks so blood flow is not meaningfully interrupted by normal movements of the patient or compressed easily from external forces. In some cases, the inflow and/or outflow conduits may come

commercially already attached to the pump. Where it is desired to implant the pump 32 and the conduits 50, 52, it is preferable that the inner diameter of the conduits be less than 25 mm, although diameters slightly larger may be effective.

In one preferred application of the present invention, the first embodiment is applied in an arterial-arterial fashion; for example, as a femoral-axillary connection, as is shown in Figure 2. It should be appreciated by one of ordinary skill in the art that an axillary-femoral connection would also be effective using the embodiments described herein. Indeed, it should be recognized by one of ordinary skill in the art that the present invention might be applied to any of the peripheral blood vessels in the patient.

The inflow conduit 50 has a first proximal end 56 that connects with the inlet 34 of the pump 32 and a second distal end 58 that connects with a first peripheral blood vessel, which is preferably the left femoral artery 26 of the patient 12, although the right femoral artery or any other peripheral artery may be acceptable. In one application, the connection between the inflow conduit 50 and the first blood vessel is via an end-to-side anastomosis, although a side-to-side anastomosis connection might be used mid-stream of the conduit where the inflow conduit were connected at its second end to an additional blood vessel or at another location on the same blood vessel (neither shown).

Similarly, the outflow conduit 52 has a first proximal end 62 that connects to the outlet 38 of the pump 32 and a second distal end 64 that connects with a second peripheral blood vessel, preferably the left axillary artery 24 of the patient 12, although the right axillary artery, or any other peripheral artery, would be acceptable. In one application, the connection between the outflow conduit 52 and the second blood vessel is via an end-to-side anastomosis, although a side-to-side anastomosis connection might be used mid-stream of the conduit where the outflow conduit were connected at its second end to yet another blood vessel (not shown) or at another location on the same blood vessel. Preferably, the outflow conduit is attached to the second blood vessel at an angle that results in the predominant flow of blood out of the pump proximally toward the aorta and heart, such as is shown in Figure 2, while still maintaining sufficient flow distally toward the hand to prevent limb ischemia.

It is preferred that application of the present invention to the peripheral blood vessels be accomplished subcutaneously; i. e., at a shallow depth just below the skin or first muscle layer so as to avoid major invasive surgery. It is also preferred that the present invention be applied extrathoracically to avoid the need to invade the patient's chest cavity. Where desired, the entire extracardiac system of the present invention 10 may be implanted within the patient 12. In that case, the pump 32 may be implanted, for example, into the groin area, with the inflow conduit 50 connected subcutaneously to, for example, the femoral artery 26 proximate the pump 32. The outflow conduit would be tunneled subcutaneously through to, for example, the left axillary artery 24. In an alternative arrangement, the pump 32 and associated drive and controller could be temporarily fastened to the exterior skin of the patient, with the inflow and outflow conduits 50, 52 connected percutaneously. In either case, the patient may be ambulatory without restriction of tethered lines.

It is contemplated that, where an anastomosis connection is not desired, a special connector may be used to connect the conduits 50, 52 to the peripheral blood vessels. With reference to Figure 3, a second embodiment of the present invention is shown, wherein the inflow conduit 50 and outflow conduit 52 are connected to the peripheral blood vessels via first and second connectors 68, 70 each comprising three-opening fittings. In the preferred embodiment, the connectors 68, 70 comprise an intra-vascular, generally-tee-shaped fitting 72 having a proximal end 74, a distal end 76, and an angled divergence 78 permitting connection to the inflow and outflow conduits 50, 52 and the blood vessels. The proximal and distal ends 74, 76 of the fittings 72 permit connection to the blood vessel into which the fitting is positioned. The angle of divergence 78 of the fittings 72 may be 90 degrees or less in either direction from the axis of flow through the blood vessel, as optimally selected to generate the needed flow distally toward the hand to prevent limb ischemia, and to insure sufficient flow and pressure toward the aorta to provide the circulatory assistance and workload reduction

needed while minimizing or avoiding endothelial damage to the vessel. In another embodiment, the connectors 68, 70 are sleeves (not shown) that surround and attach to the outside of the peripheral blood vessel where, within the interior of the sleeve, a port to the blood vessel is provided to permit blood flow from the conduits 50, 52 when they are connected to the connectors 68, 70, respectively.

Other types of connectors having other configurations are contemplated that may avoid the need for an anastomosis connection or that permit connection of the conduits to the blood vessels. For example, it is contemplated that an L-shaped connector be used if it is desired to withdraw blood more predominantly from one direction of a peripheral vessel or to direct blood more predominantly into a peripheral vessel. Referring to Figure 7, an inflow conduit 50 is fluidly connected to a peripheral vessel, for example, the left femoral artery 26, using an L-shaped connector 310. The connector 310 has an inlet port 312 at a proximal end and an outlet port 314 through which blood flows into the inflow conduit 50. The connector 310 also has an arrangement of holes 316 within a wall positioned at a distal end opposite the inlet port 312 so that some of the flow drawn into the connector 310 is diverted through the holes 312, particularly downstream of the connector, as in this application. A single hole in the wall could also be effective, depending upon size and placement. The connector may be a deformable L-shaped catheter percutaneously applied to the blood vessel or, in an alternative embodiment, be connected directly to the walls of the blood vessel for more long term application. By directing some blood flow downstream of the connector during withdrawal of blood from the vessel, ischemic damage downstream from the connector may be avoided. Such ischemic damage might otherwise occur if the majority of the blood flowing into the inflow connector were diverted from the blood vessel into the inflow conduit. It is also contemplated that a connection to the blood vessels might be made via a cannula, wherein the cannula is implanted, along with the inflow and outflow conduits.

The advantage of discrete connectors is their potential application to patients with chronic CHF. A connector eliminates a need for an anastomosis connection between the conduits of the present invention system and the peripheral blood vessels where it is desired to remove and/or replace the system more than one time. The connectors could be applied to the first and second blood vessels semi-permanently, with an end cap applied to the divergence for later quick-connection of the present invention system to the patient. In this regard, a patient might experience the benefit of the present invention periodically, without having to reconnect and redisconnect the conduits from the blood vessels via an anastomosis procedure each time. Each time it is desired to implement the present invention, the end caps would be removed and the conduit attached to the connectors quickly.

In the preferred embodiment of the connector 70, the divergence 78 is oriented at an acute angle significantly less than 90° from the axis of the fitting 72, as shown in Figure 3, so that a majority of the blood flowing through the outflow conduit 52 into the blood vessel (e. g., left axillary 24) flows in a direction proximally toward the heart 14, rather than in the distal direction. In an alternative embodiment, the proximal end 74 of the fitting 72 may have a diameter larger than the diameter of the distal end 76, without need of having an angled divergence, to achieve the same result.

With or without a connector, with blood flow directed proximally toward the aorta, the result may be concurrent flow down the descending aorta, which will result in the reduction of pressure at the aortic root. Thus, the present invention may be applied so to reduce the afterload on the patient's heart, permitting at least partial if not complete CHF recovery, while supplementing blood circulation. Concurrent flow depends upon the phase of operation of the pulsatile pump and the choice of second blood vessel to which the outflow conduit is connected.

While the present invention may be applied to create an arterial-arterial flow path, given the nature of the present invention, i. e., supplementation of circulation to meet organ demand, a venous-arterial flow path may also be used. For example, with reference to Figure 4, one embodiment of the present invention 10 may be applied to the patient 12 such that the inflow conduit 50 is connected to a peripheral vein, such as the left femoral vein 80. In this arrangement, the outflow conduit 50 may be connected to one of the

peripheral arteries, such as the left axillary 24. Arterial-venous arrangements are contemplated as well. In those venous-arterial cases where the inflow is connected to a vein and the outflow is connected to an artery, the pump 32 should be sized to permit flow sufficiently small so that oxygen-deficient blood does not rise to unacceptable levels in the arteries. It should be appreciated that the connections to the peripheral veins could be by one or more methods described above for connecting to a peripheral artery. It should also be appreciated that the present invention could be applied as a venous-venous flow path, wherein the inflow and outflow are connected to separate peripheral veins. In addition, an alternative embodiment comprises two discrete pumps and conduit arrangements, one being applied as a venous-venous flow path, and the other as an arterial-arterial flow path. When venous blood is mixed with arterial blood either at the inlet of the pump or the outlet of the pump the ratio of venous blood to arterial blood should be controlled to maintain an arterial saturation of a minimum of 80% at the pump inlet or outlet. Arterial saturation can be measured and/or monitored by pulse oximetry, laser doppler, colorimetry or other methods used to monitor blood oxygen saturation. The venous blood flow into the system can then be controlled by regulating the amount of blood allowed to pass through the conduit from the venous-side connection.

A partial external application of the present invention is contemplated where a patient's heart failure is acute; i. e., is not expected to last long, or in the earlier stages of heart failure (where the patient is in New York Heart Association Classification (NYHAC) functional classes II or III). With reference to Figure 5, a third embodiment of the present invention 110 is applied percutaneously to a patient 112 to connect two peripheral blood vessels wherein a pump 132 and its associated driving means and controls are employed extracorporeally. The pump 132 has an inflow conduit 150 and an outflow conduit 152 associated therewith for connection to two peripheral blood vessels. The inflow conduit 150 has a first end 156 and second end 158 wherein the second end is connected to a first peripheral blood vessel (e. g., femoral artery 126) by way of a cannula 180. The cannula 180 has a first end 182 sealably connected to the second end 158 of the inflow conduit 150. The cannula 180 also has a second end 184 that is inserted through a surgical opening 186 or an introducer sheath (not shown) and into the blood vessel source (e. g., femoral artery 126).

Similarly, the outflow conduit 152 has a first end 162 and second end 164 wherein the second end is connected to a second peripheral blood vessel (e. g., left axillary artery 124) by way of a cannula 180. Like the inflow cannula, the outflow cannula 180 has a first end 182 sealably connected to the second end 164 of the outflow conduit 152. The outflow cannula 180 also has a second end 184 that is inserted through surgical opening 190 or an introducer sheath (not shown) and into the second blood vessel (e. g., left axillary artery 124). By use of a percutaneous application, the present invention may be applied temporarily without the need to implant any aspect thereof or to make anastomosis connections to the blood vessels.

It is contemplated that a means for minimizing the loss of thermal energy in the patient's blood be provided where the present inventive system is applied extracorporeally. Such means for minimizing the loss of thermal energy may comprise, for example, a heated bath through which the inflow and outflow conduits pass or, alternatively, thermal elements secured to the exterior of the inflow and outflow conduits. Referring to Figure 9, one embodiment comprises an insulating wrap 402 surrounding the outflow conduit 152 having one or more thermal elements passing therethrough. The elements may be powered, for example, by a battery (not shown). One advantage of thermal elements is that the patient may be ambulatory, if desired. Other means that are known by persons of ordinary skill in the art for ensuring that the temperature of the patient's blood remains at acceptable levels while travelling extracorporeally are also contemplated.

An alternative variation of the third embodiment may be used where it is desired to treat a patient periodically, but for short periods of time each occasion and without the use of special connectors. With this variation, it is contemplated that the second ends of the inflow and outflow conduits be more permanently connected to the associated blood vessels via, for example, an enastomosis

connection, wherein a portion of each conduit proximate to the blood vessel connection is implanted percuteneously with a removable cap enclosing the externally-exposed first and (or an intervening end thereof) of the conduit external to the patient. When it is desired to provide a circulatory flow path to supplement blood flow, the removable cap on each exposed percutaneously-positioned conduit could be removed and the pump (or the pump with a length of inflow and/or outflow conduit attached thereto) inserted between the exposed percutaneous conduits. In this regard, a patient may experience the benefit of the present invention periodically, without having to reconnect and rediscconnect the conduits from the blood vessels each time.

Another embodiment of the present invention includes a plurality of inflow and/or outflow conduits. For example, with reference to Figure 6, a fourth embodiment of the present invention 210 includes a pump 232 in fluid communicetion with a plurality of inflow conduits 250A, 250B and a plurality of outflow conduits 252A, 252B. Each pair of conduits converges at a generally Y-shaped convergence 286 that converges the flow at the inflow end and diverges the flow at the outflow end. Each conduit may be connected to a separate peripheral blood vessel, although it is possible to have two connections to the same blood vessel at remote locations. In one arrangement, all four conduits are connected to peripheral arteries. Alternatively, one or more of the conduits could be connected to veins. In the application shown in Figure 6, inflow conduit 250A is connected to left femoral artery 226 while inflow conduit 250B is connected to left femoral vein 278. Outflow conduit 252A is connected to left exillary artery 224 while outflow conduit 252B is connected to left carotid artery 222. It should be noted that the connections of eny or all of the conduits to the blood vessels may be via an anastomosis connection or via a special connector, as described above. In addition, the embodiment of Figure 6 may be applied to any combination of peripheral blood vessels that would best suit the patient's condition. For example, it may be desired to heve one inflow conduit and two outflow conduits or vice versa. It should be noted that more than two conduits mey be used on the inflow or outflow side, where the number of inflow conduits is not necessarily equal to the number of outflow conduits.

If desired, the present inventive system may further comprise a reservoir that is either contained within or in fluid communication with the inflow conduit. This reservoir is preferably made of materials that are nonthrombogenic. Referring to Figure 9, a reservoir 420 is positioned fluidly in line with the inflow conduit 150. The reservoir 420 serves to sustain adequate blood in the system when the pump demand exceeds momentarily the volume of blood available in the peripheral blood vessel in which the inflow conduit resides until the pump output can be adjusted. The reservoir reduces the risk of excessive drainage of blood from the peripheral blood vessel, which may occur when cardiac output falls farther than the already diminished baseline level of cardiac output, or when there is systemic vasodilation, as can occur, for example, with septic shock. It is contemplated that the reservoir would be primed with an acceptable solution, such as saline, when the present system is first applied to the patient.

In an alternative embodiment, the present system comprises a multi-lumen catheter whereby the system may be applied by insertion at a single cannulated site while the inflow and outflow conduits still fluidly communicate with peripheral vessels. Referring to Figure 8, a multi-lumen catheter 510 could be inserted, for example, into the left femoral artery 26 and guided superiorly through the descending aorta to one of numerous locations. The blood could discharge, for example, directly into the descending aorte proximate an arterial branch, such as the left subclavian artery or, as shown in Figure 2 by way of example, directly into the peripheral mesenteric artery 30. Preferably, the multi-lumen catheter 510 has an inflow port 512 that may be positioned within the left femoral artery 26 when the catheter 510 is fully inserted so that blood drawn from the left femoral artery is directed through the inflow port 512 into a first lumen 514 in the catheter. This blood is then pumped through a second lumen 516 in the catheter and out through an outflow port 520 at the distal end of the catheter 510. The outflow port 520 may be situated within, for example, the mesenteric artery 30 such that blood flow results from the left femoral artery 26 to the mesenteric artery 30. Preferably, where there is a desire for the patient to

be ambulatory, the multi-lumen catheter 510 should preferably be made of material sufficiently flexible and resilient to permit the patient to be comfortably move about while the catheter is indwelling in the patient's blood vessels without causing any vascular trauma.

As explained above for several embodiments, one of the advantages of the present heart assist system is that it permits the patient to be ambulatory. If desired, the system may be designed portably so that it may be carried directly on the patient. Referring to Figure 9, this may be accomplished through the use of a portable case 610 with a belt strap 612 to house the pump, power supply and/or the controller, along with certain portions of the inflow and/or outflow conduits, if necessary. It may also be accomplished with a shoulder strap or other techniques, such as a backpack or a fanny pack, that permit effective portability. As shown in Figure 9, blood is drawn through the inflow conduit 150 into a pump contained within the portable case 610, where it is discharged into the outflow conduit 152 back into the patient.

While the above description has explained the inventive features of the invention as applied to various embodiments, it will be understood that the variations in the form and details of the apparatus or method may be made by those of ordinary skill in the art without departing from the spirit of the invention. The scope of the invention is indicated by the appended claims herein, however, not by the foregoing description.

WHAT IS CLAIMED IS:

1. An extracardiac pumping system (10) comprising a pump (32), an inflow conduit (50) fluidly coupled to the pump to direct blood to the pump, and an outflow conduit (52) fluidly coupled to the pump to direct blood away from the pump, said extracardiac pumping system (10) characterized by said pump being configured to pump blood at an average volumetric rate of 3.0 liters/min. and below for a sustained period of time to direct blood between a first and second non-primary blood vessel to supplement blood circulation through a patient, said inflow conduit being configured to couple to the first blood vessel subcutaneously and having an inner diameter of no greater than about 25 millimeters, and said outflow conduit being configured to couple to the second blood vessel subcutaneously and having an inner diameter of no greater than about 25 millimeters, and a reservoir (42) fluidly coupled to the inflow conduit, said reservoir being adapted to house a volume of blood from which the pump may draw blood, with the proviso that no oxygenator is present in the system.

2. An extracardiac pumping system (10) comprising a pump (32), an inflow conduit (50) fluidly coupled to the pump to direct blood to the pump, and an outflow conduit (52) fluidly coupled to the pump to direct blood away from the pump, said extracardiac pumping system (10) characterized by said pump being configured to pump blood at an average volumetric rate of 3.0 liters/min. and below for a sustained period of time to direct blood between a first and second non-primary blood vessel to supplement blood circulation through a patient, said inflow conduit being configured to couple to the first blood vessel subcutaneously and having an inner diameter of no greater than about 25 millimeters, said outflow conduit being configured to couple to the second blood vessel subcutaneously and having an inner diameter of no greater than about 25 millimeters, and a multi-lumen catheter (510) housing at least two lumens, a first lumen (512) fluidly connected to the inflow conduit and a second lumen (516) fluidly connected to the outflow conduit, at least one lumen also fluidly communicating with a non-primary blood vessel, with the proviso that no oxygenator is present in the system.

3. An extracardiac pumping system (10) comprising a pump (32), an inflow conduit (50) fluidly coupled to the pump to direct blood to the pump, and an outflow conduit (52) fluidly coupled to the pump to direct blood away from the pump, said extracardiac pumping system (10) characterized by said pump being configured to pump blood at an average volumetric rate of 3.0 liters/min. and below for a sustained period of time to direct blood between a first and second non-primary blood vessel to supplement blood circulation through a patient, said inflow conduit being configured to couple to the first blood vessel subcutaneously and having an inner diameter of no greater than about 25 millimeters, said outflow conduit being configured to couple to the second blood vessel subcutaneously and having an inner diameter of no greater than about 25 millimeters, at least one of said conduits having a port (310) at one end, said port (31) having a wall with at least one hole therein (316), with the proviso that no oxygenator is present in the system.

4. An extracardiac pumping system (10) comprising a pump (32), an inflow conduit (50) fluidly coupled to the pump to direct blood to the pump, and an outflow conduit (52) fluidly coupled to the pump to direct blood away from the pump, said extracardiac pumping system (10) characterized by said pump being configured to pump blood at an average volumetric rate of 3.0 liters/min. and below for a sustained period of time to direct blood between a first and second non-primary blood vessel to supplement blood circulation through a patient, said inflow conduit being configured to couple to the first blood vessel subcutaneously and having an inner diameter of no greater than about 25 millimeters, said outflow conduit being configured to

couple to the second blood vessel subcutaneously and having an inner diameter of no greater than about 25 millimeters, and a device (402) for minimizing heat loss from blood that flows through the system extracorporeally, with the proviso that no oxygenator is present in the system.

5. An extracardiac pumping system (10) comprising a pump (32), an inflow conduit (50) fluidly coupled to the pump to direct blood to the pump, and an outflow conduit (52) fluidly coupled to the pump to direct blood away from the pump, said extracardiac pumping system (10) characterized by said pump being configured to pump blood at an average volumetric rate of 3.0 liters/min. and below for a sustained period of time to direct blood between a first and second non-primary blood vessel to supplement blood circulation through a patient, said inflow conduit being configured to couple to the first blood vessel subcutaneously and having an inner diameter of no greater than about 25 millimeters, said outflow conduit being configured to couple to the second blood vessel subcutaneously and having an inner diameter of no greater than about 25 millimeters, and device (610) for portably carrying a portion of the extracardiac system that resides extracorporeally on the patient, the device (610) configured to carry at least the pump of said system, with the proviso that no oxygenator is present in the system.

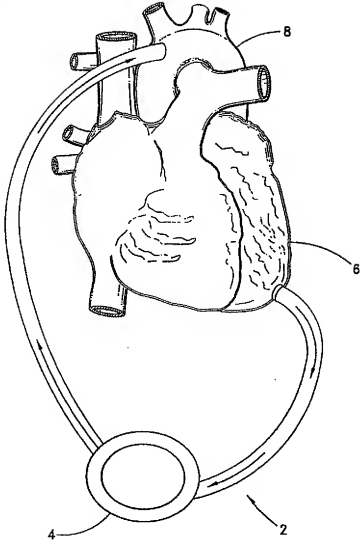


FIG. 1

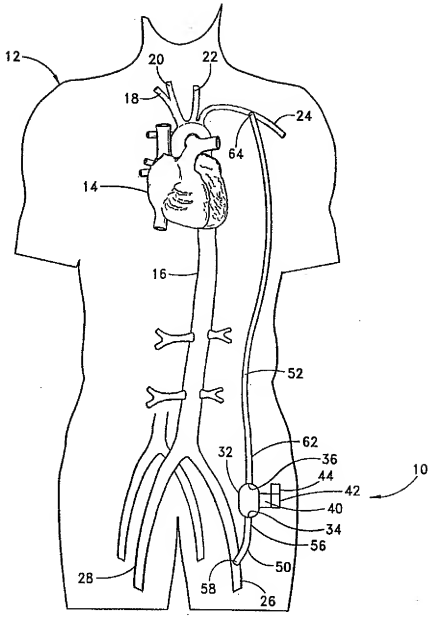


FIG. 2

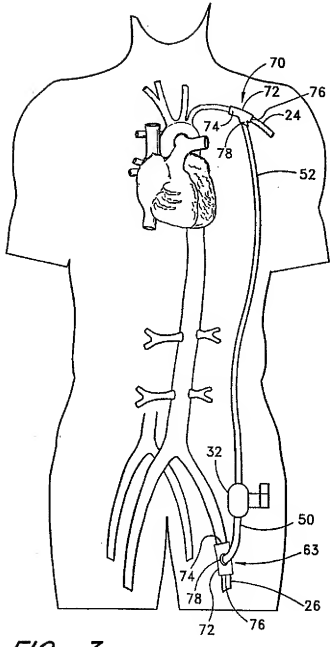


FIG. 3

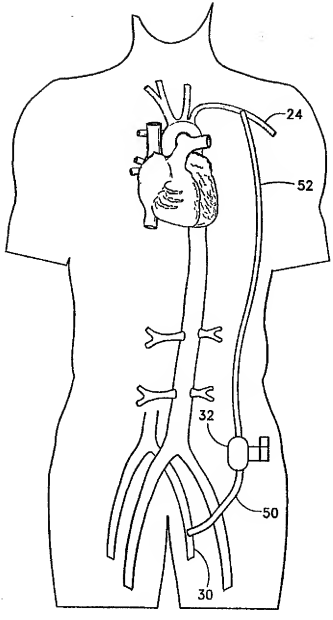
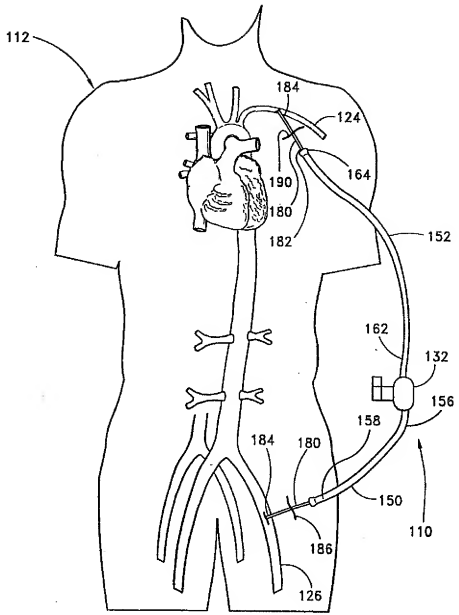


FIG. 4


112
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126

FIG. 5

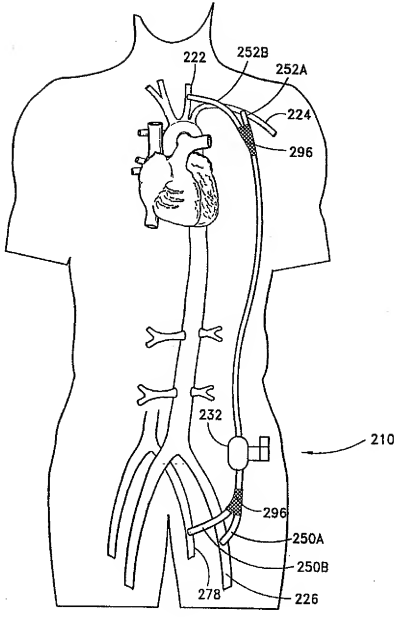

FIG. 6

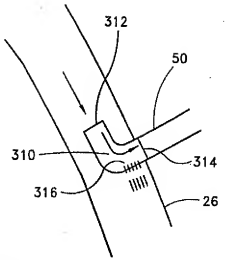

FIG. 7

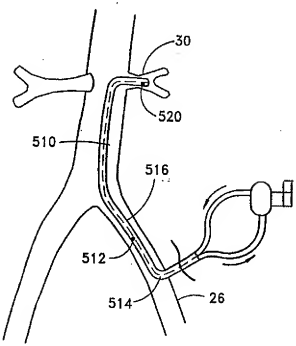

FIG. 8

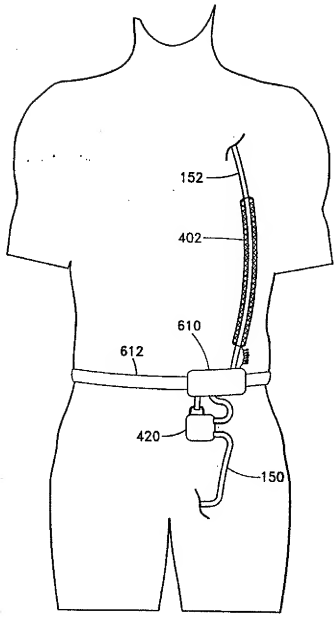

FIG. 9

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 00/06749

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/10 A61M1/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2 935 068 A (DONALDSON) 3 May 1960 (1960-05-03) the whole document	1-5
A	EP 0 411 605 A (TERUMO KABUSHIKI KAISHA) 6 February 1991 (1991-02-06) column 13, line 3 -column 15, line 57 figures 7,8	1-5
P,A	WO 99 19010 A (FORE FLOW CORPORATION) 22 April 1999 (1999-04-22) the whole document	1-5
A	US 4 957 504 A (CARDACK WILLIAM) 18 September 1990 (1990-09-18) column 5, line 12 - line 29 figure 4	1-5

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 June 2000	27/06/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Schönleben, J

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Inter onal Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	EP 0 405 749 A (PHILLIPS) 2 January 1991 (1991-01-02) abstract figures 1-3	2
A	WO 98 14225 A (ALESI ET AL.) 9 April 1998 (1998-04-09) figure 10	5

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